FEB 2 4 2012 K113190

Meridian Bioscience, Inc.	510(k) Application TRU Legionella	
	Description:	510(k) Summary
	Identification:	Attachment 002
	Date:	October 28, 2011

510(k) number: _____ **Date of Preparation:** October 28, 2011

Submitter:	**Meridian Bioscience, Inc**
Submitter's address:	3471 River Hills Drive Cincinnati, Ohio 45244
Contact:	Susan Bogar
Contact number:	(513) 271-3700
Device name:	TRU Legionella
Common name:	Device Legionella, Spp., Elisa
Classification:	Haemophilus spp serological reagents MJH, CFR Section 866.3300
Predicate device:	K982238: Binax NOW® Legionella
Reference comparator:	Binax NOW® Legionella

Description of the Device

The TRU Legionella assay is an in vitro, rapid, lateral-flow immunoassay for the qualitative detection of *Legionella pneumophila* serogroup 1 antigen in human urine specimens. The assay consists of Test Strips containing anti-*Legionella pneumophila* serogroup 1 as the capture antibody, Conjugate Tubes containing anti-*Legionella pneumophila* serogroup 1 as the detection antibody, Sample Diluent/Negative Control, and Positive Control.

Intended Use

The TRU Legionella assay is an in vitro, rapid, lateral-flow immunoassay for the qualitative detection of *Legionella pneumophila* serogroup 1 antigen in human urine specimens. It is designed to test specimens from patients with symptoms of pneumonia. Test results are to be used as an aid in diagnosis of *Legionella pneumophila* serogroup 1 infection. A negative result does not preclude infection with *Legionella pneumophila* serogroup 1. Test results are to be used in conjunction with information obtained from the patient's clinical evaluation and other diagnostic procedures.

Table 1: Comparison to Predicate Device

Characteristic	TRU Legionella	BinaxNOW® *Legionella*
Test Format	Rapid lateral flow immunoassay	Rapid immunochromatographic membrane assay
Intended Use		
Qualitative/Quantitative	Qualitative	Qualitative
Target Antigen	*Legionella pneumophila* serogroup 1	*Legionella pneumophila* serogroup 1
Specimen Types	Human urine, preserved and unpreserved	Human urine, preserved and unpreserved
Reagents/Components	Test Strip Conjugate Tube Sample Diluent/Negative Control Positive Control Plastic transfer pipettes with 100, 200 and 300 µL volume marks	Test Device Reagent A Positive Control Swab Negative Control Swab Swabs
Antibody Sources		
Test Card	Rabbit polyclonal	Rabbit polyclonal
Conjugate	Rabbit polyclonal	Polyclonal
Sample Preparation		
Unpreserved and preserved urine	1. Add 100 µL of Sample Diluent to Conjugate Tube. Vortex for 10 seconds. 2. Add 100 µL of thoroughly mixed urine sample to the Conjugate Tube. 3. Mix sample and conjugate thoroughly.	1. Dip swab into the urine sample and then insert swab into the bottom hole of the Test Device. 2. Add 2 drops of Reagent A to the bottom hole.
Testing Time	Approximately 20 minutes	Approximately 15 minutes
Equipment		
General Laboratory Equipment	Vortex Interval timer Disposable latex gloves	Timer Urine collection container BinaxNOW® *Legionella* Urinary Antigen Control Swab Pack
Reading Method	Visual	Visual
Results Interpretation		
Visual Read	**Negative:** A PINK-RED band at the Control Line position. No other bands are present. **Positive:** PINK-RED band of any color intensity at the Control and Legionella Test Line positions. **Invalid:** No band at the Control Line position, a pink-red band appearing after 21 minutes of incubation, or a band of any other color than pink-red.	**Negative:** Single pink to purple colored Control line visible in the top half of the window. **Positive:** Two pink to purple colored lines. **Invalid:** No line at the Control Line position or no lines at the Control or Sample Line positions.

Performance Comparison, Non-Clinical Tests

Analytical Sensitivity

Sensitivity studies were designed to determine with 95% confidence the analytical limit of detection (LoD) of *L. pneumophila* Philadelphia and Bellingham strains diluted in a human urine matrix. The analytical sensitivity of this assay was based on 45 replicates for each measurand and with a stated probability (95%) of obtaining positive responses at the following levels of the measurand shown in Table 1.

Table 2: Analytical Sensitivity

Strain ID	Limit of Detection (LoD)
Philadelphia strain (Pontiac subgroup; ATCC 33152)	3.76×10^5 CFU/mL
Bellingham strain (non-Pontiac subgroup; NCTC 11404)	5.2×10^5 CFU/mL

Interference Testing

Selected drugs and other non-microbial substances that might be present in urine samples from healthy persons or patients suspected of having *L. pneumophila* infection were added to three natural negative and three contrived positive samples. The contrived positive samples were prepared by spiking confirmed negative samples with *Legionella pneumophila* Philadelphia strain antigen at 3.76×10^5 CFU/mL, the limit of detection for this assay. Dilution Controls for each sample were prepared by adding a saline solution in place of the potentially interfering substance.

The following substances, at the specified saturated solvent/diluent concentrations, do not interfere with the test results in the final concentrations listed:
Antihistamine (0.22 mg/mL), Ascorbic acid (1.0 mg/mL), Bilirubin (0.2 mg/mL), Boric acid (2.63 mg/mL) Ciprofloxacin (0.22 mg/mL), Cold and flu tablets (50 mg/ml), Cough drops (0.22 mg/mL), Cough syrup (0.20 mg/mL), Decongestant (0.22 mg/mL), Erythromycin (0.067 mg/mL), Glucose (20 mg/mL), Protein (BSA) (5 mg/mL), Rifampicin (0.09 mg/mL), Urea (20 mg/mL), White blood cells (10%), Whole blood (10%).

Cross-reactivity Study

Potentially cross-reactive microorganisms that might be present in urine samples from healthy persons or patients suspected of having *L. pneumophila* infection were added at a final concentration of 1.2×10^8 CFU/mL (bacteria or fungi) or a final concentration greater than 1×10^5 $TCID_{50}$/mL (viruses) to a pooled negative and a contrived positive sample. The negative specimen was prepared from a pool of donor urine that was confirmed negative. The contrived positive sample was prepared by spiking a confirmed negative sample with *Legionella pneumophila* Philadelphia strain antigen at 3.76×10^5 CFU/mL, the limit of detection for this assay. Dilution controls for each sample were prepared by adding a saline solution in place of the potentially cross-reactive organisms.

The following microorganisms, at the indicated concentrations, do not interfere with TRU Legionella test results: *Alcaligenes faecalis, Bacillus cereus, Bacillus subtilis, Candida albicans, Candida glabrata, Candida parapsilosis, Citrobacter freundii, Enterobacter aerogenes, Enterobacter cloacae, Enterococcus faecalis, Enterococcus faecium, Escherichia coli, Haemophilus influenzae, Klebsiella pneumoniae, Legionella bozemanii, Legionella dumoffii, Legionella feeleii, Legionella gormanii, Legionella longbeachae, Legionella micdadei, Legionella pneumophila serogroup 2, Legionella pneumophila serogroup 3, Legionella pneumophila serogroup 4, Legionella pneumophila serogroup 5, Legionella pneumophila serogroup 6, Morganella morganii, Moraxella osloensis, Nocardia asteroides, Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Serratia liquefaciens, Serratia marcescens, Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus saprophyticus, Streptococcus* groups A, B, D, F, G, *Streptococcus pneumoniae*, Adenovirus, Coxsackievirus, Influenza A, Influenza B, Parainfluenza Virus, Respiratory Syncytial Virus A, Respiratory Syncytial Virus B.

Strain Reactivity

The following *L. pneumophila* stock cultures from different sources were tested and produced positive reactions at concentrations of 4.8×10^6 CFU/mL or lower with the TRU Legionella assay:

Pontiac subgroup: CCUG 13395; NCTC 12024, Allentown 1; NCTC 12006, Benidorm; CCUG 33058, Knoxville; NCTC 12007, France.

Non-Pontiac subgroup: NCTC 12008, OLDA; NCTC 12098, Camperdown; NCTC 12025, Heysham; NCTC 12009, Oxford.

Performance Comparison, Clinical Tests

Clinical trials for the TRU Legionella assay were conducted August – October 2011. Performance characteristics of the TRU Legionella assay were determined by comparison to the Binax NOW *Legionella* Urinary Antigen test. Independent clinical test sites located in the Southeastern and Midwestern regions of the United States and an independent test site in the Netherlands evaluated a total of 428 qualified patient samples. The US clinical trial sites evaluated both retrospective frozen samples and prospectively collected samples; the retrospective samples were samples that had been previously submitted for *Legionella* testing. The site located in the Netherlands evaluated 220 frozen samples, chosen from a well characterized repository of urine samples collected from patients with confirmed Legionnaires Disease as well as negative specimens from patients suspected of infection by *Legionella*. Samples were collected from 272 (63.6%) males and 134 (31.3%) females. The age groups of patients ranged from 6 years to 96 years. Overall positive percent agreement was determined to be 96.3%; overall negative percent agreement was determined to be 100.0%. Subsequent tables show overall assay performance as well as performance by clinical site.

Table 3: Comparison of TRU Legionella to Binax NOW *Legionella* (Retrospective and Prospective Specimens)

	TRU Legionella		
Binax NOW	**Positive**	**Negative**	**Total**
Positive	131	5	136
Negative	0	292	292
Total	131	297	428
			95% CI
Positive Agreement	131/136	96.3%	91.7 – 98.4%
Negative Agreement	292/292	100.0%	98.7 – 100.0%
Correlation	423/428	98.8%	97.3 – 99.5%

Table 4: Performance Characteristics by Site (Retrospective and Prospective Specimens)

Clinical Trial Site	TRU Legionella /Binax NOW	Positive Agreement (%)	95% CI	TRU Legionella /Binax NOW	Negative Agreement (%)	95% CI
Site 1	6/6	100.0%	61.0 – 100.0%	60/60	100.0%	94.0 – 100.0%
Site 2	103/108	95.4%	89.6 – 98.0%	104/104	100.0%	96.4 - 100.0%
Site 3	3/3	100.0%	43.9 – 100.0%	78/78	100.0%	93.5 – 100.0%
Site 4	19/19	100.0%	83.2 – 100.0%	50/50	100.0%	92.9 – 100.0%

Reproducibility

Reproducibility panels were performance by three clinical laboratories using blind coded panels. Samples were randomly sorted within each panel to mask identities. Each panel consisted of 3 contrived moderately positive specimens, 3 contrived low positive samples, 3 contrived samples containing Legionella-negative specimens at or near the assay cutoff, and 1 natural negative specimen. Panels were tested at three independent laboratories; each laboratory tested two panels twice each day over five days. The overall correlation for the TRU Legionella reproducibility study was 100% (98.7 – 100.0%). The correlation between expected and achieved results for the moderate positive, low positive and weak negative specimens was 100.0% (98.2 – 100.0%). The correlation for the high negative specimen was 100.0% (95.9 – 100.0%). Tables 5-7 contain the reproducibility data for the three sites.

Table 5: Site 1 Reproducibility Data, Lot 751930B002

Sample ID	Sample Result	Day 1 Run 1 (HBD-S)*	Day 1 Run 2 (DM)*	Day 2 Run 1 (HBD-S)*	Day 2 Run 2 (DM)*	Day 3 Run 1 (HBD-S)*	Day 3 Run 2 (DM)*	Day 4 Run 1 (HBD-S)*	Day 4 Run 2 (DM)*	Day 5 Run 1 (HBD-S)*	Day 5 Run 2 (DM)*
Positive Control	Positive	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Negative Control	Negative	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Moderate Positive 1	Positive	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Moderate Positive 2		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Moderate Positive 3		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 1	Positive	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 2		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 3		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
High Negative 1	Negative	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
High Negative 2		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
High Negative 3		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Negative 1	Negative	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Percent Correlation		100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Correlation of cut off Specimens		100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Legend: Pos = Positive; Neg = Negative

* Initials of person performing testing.

Interpretation of Results:

Positive Test Result: Pink-red band of any color intensity at the Control and Test line positions.

Negative Test Result: Pink-red band at the Control line position only.

Invalid Test Result: No band at the Control line position, a pink-red band appearing at the Test line position after 21 minutes of incubation, or a band of any color other than pink-red.

Table 6: Site 2 Reproducibility Data, Lot 751930B003

Sample ID	Sample Result	Day 1 Run 1 (CM)*	Day 1 Run 2 (LR)*	Day 2 Run 1 (CM)*	Day 2 Run 2 (LR)*	Day 3 Run 1 (CM)*	Day 3 Run 2 (LR)*	Day 4 Run 1 (CM)*	Day 4 Run 2 (LR)*	Day 5 Run 1 (CM)*	Day 5 Run 2 (LR)*
Positive Control	Positive	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Negative Control	Negative	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Moderate Positive 1	Positive	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Moderate Positive 2		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Moderate Positive 3		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 1	Positive	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 2		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 3		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
High Negative 1	Negative	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
High Negative 2		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
High Negative 3		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Negative 1	Negative	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Percent Correlation		100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Correlation of cut off Specimens		100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Legend: Pos = Positive; Neg = Negative

* Initials of person performing testing.

Interpretation of Results:

Positive Test Result: Pink-red band of any color intensity at the Control and Test line positions.

Negative Test Result: Pink-red band at the Control line position only.

Invalid Test Result: No band at the Control line position, a pink-red band appearing at the Test line position after 21 minutes of incubation, or a band of any color other than pink-red.

Table 7: Site 3 Reproducibility Data, Lot 751930B001

Sample ID	Sample Result	Day 1 Run 1 (BD)*	Day 1 Run 2 (JH)*	Day 2 Run 1 (BD)*	Day 2 Run 2 (JH)*	Day 3 Run 1 (BD)*	Day 3 Run 2 (JH)*	Day 4 Run 1 (BD)*	Day 4 Run 2 (JH)*	Day 5 Run 1 (BD)*	Day 5 Run 2 (JH)*
Positive Control	Positive	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Negative Control	Negative	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Moderate Positive 1	Positive	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Moderate Positive 2		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Moderate Positive 3		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 1	Positive	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 2		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 3		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
High Negative 1	Negative	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
High Negative 2		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
High Negative 3		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Negative 1	Negative	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Percent Correlation		100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Correlation of cut off Specimens		100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Legend: Pos = Positive; Neg = Negative

* Initials of person performing testing.

Interpretation of Results:

Positive Test Result: Pink-red band of any color intensity at the Control and Test line positions.

Negative Test Result: Pink-red band at the Control line position only.

Invalid Test Result: No band at the Control line position, a pink-red band appearing at the Test line position after 21 minutes of incubation, or a band of any color other than pink-red.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Meridian Bioscience, Inc.
c/o Ms. Susan Bogar
Product Quality Assurance Manager
3471 River Hills Drive
Cincinnati, OH 45244

FEB 2 4 2012

Re: K113190
Trade/Device Name: TRU Legionella assay
Regulation Number: 21 CFR 866.3300
Regulation Name: Haemophilus spp. Serological Reagents
Regulatory Class: Class II
Product Code: MJH
Dated: January 26, 2012
Received: January 27, 2012

Dear Ms. Bogar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

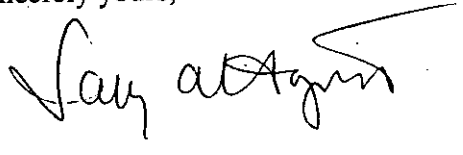
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice

requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K 113190

Device Name: TRU Legionella

Indications for Use:

The TRU Legionella assay is an in vitro, rapid, lateral-flow immunoassay for the qualitative detection of *Legionella pneumophila* serogroup 1 antigens in human urine specimens. It is designed to test specimens from patients with symptoms of pneumonia. Test results are to be used as an aid in diagnosis of *Legionella pneumophila* serogroup 1 infection. A negative result does not preclude infection with *Legionella pneumophila* serogroup 1. Test results are to be used in conjunction with information obtained from the patient's clinical evaluation and other diagnostic procedures.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Freddie M. Cooke

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K 113190